

JAN 16 2004

**Section 5**

**510 (k) SUMMARY**

- 1. Applicant:** Bisco, Inc  
1100 West Irving Park Road  
Schaumburg, IL 60193
- Contact Person:** Benjamin Lichtenwalner  
Ph. 847-534-6146  
Fax 847-534-6111
- Prepared Date:** November 12, 2003
- 2. Device Trade Name:** **DIAPEX**  
**Common/Usual Name:** Calcium/Iodoform Root Canal Treatment Paste  
**Classification/Name:** Class II per 21 CFR 872.3820 Root Canal Filling Resin
- 3. Predicate Device:** Vitapex Pre-loaded dental syringe from Neo Dental Chemical Products, cleared under K973667 dated 11/6/1997.
- 4. Description of Application Device:**  
DIAPEX is a yellow radiopaque calcium hydroxide paste with iodoform, used as a root canal filling material. It is packaged as a 2 gm syringe. Intraoral application uses enclosed disposable intracanal tips.
- 5. Intended Uses of Applicant Device:**  
DIAPEX is used to stimulate the healing process due to the mixture of calcium hydroxide and iodoform and the induction effect of these two ingredients. DIAPEX is used to promote healing effects and to help prevent bacterial contamination of the canal, as the two main ingredients improve the induction effect for hard tissue induction and deposition. DIAPEX can also be used as a medicament for the treatment of infected root canals, and as a permanent, low volume additive to the filling process of a treated root canal to assist in the induction and deposition of hard tissue to make the healing process more rapid and complete. The use of DIAPEX in the treatment of infected root canals, or following pulpectomy, or for the apexogenesis or apexification, and/or for the tip filling of prepared, treated root canals at the time of final filling with gutta-percha is also indicated.
- 6. Technological Characteristics:**
- | Technological Characteristic   | Vitapex                            | DIAPEX                             |
|--------------------------------|------------------------------------|------------------------------------|
| Intended use                   | Rood Canal Filling Material        | Rood Canal Filling Material        |
| Chemical composition           | Calcium Hydroxide / Iodoform Paste | Calcium Hydroxide / Iodoform Paste |
| Mechanical/Physical properties | Yellow Radiopaque Paste            | Yellow Radiopaque Paste            |

Side by side comparisons of DIAPEX to the predicate device Vitapex Pre-loaded dental syringe from Neo Dental Chemical Products clearly demonstrates that the applicant device is substantially equivalent to the legally marked device. It is concluded that the information supplied in this submission has proven the safety and efficacy of DIAPEX.

**DEPARTMENT OF HEALTH & HUMAN SERVICES****Public Health Service****JAN 16 2004**

**Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850**

Mr. Benjamin Lichtenwalner  
Regulatory Affairs Coordinator  
Bisco, Incorporated  
1100 West Irving Park Road,  
Schaumburg, Illinois 60193

Re: K033585

Trade/Device Name: DIAPEX  
Regulation Number: 872.3820  
Regulation Name: Root Canal Filling Resin  
Regulatory Class: II  
Product Code: K1F  
Dated: November 12, 2003  
Received: November 13, 2003

Dear Mr. Lichtenwalner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address  
<http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K033585

## Indications for Use

510(k) Number (if known): **K033585**

Device Name: **DIAPEX**

Indications For Use:

1. For use to stimulate the healing process due to the mixture of calcium hydroxide and iodoform and the induction effect of these two ingredients.
2. Used to promote healing effects and to help prevent bacterial contamination of the canal, as the two ingredients improve the induction effect for hard tissue induction and deposition.
3. To be used as a medicament for the treatment of infected root canals, and as a permanent, low volume additive to the filling process of a treated root canal to assist in the induction and deposition of hard tissue to make the healing process more rapid and complete.
4. For use in the treatment of infected root canals, or following pulpectomy, or for the apexogenesis or apexification, and/or for the tip filling of prepared, treated root canals at the time of final filling with gutta-percha.

These indications include application in:

1. Intracanal Medicament
2. Apexification
3. Periapical Lesions
4. Root Resorption
5. Temporary Root Filling
6. Perforations
7. Underdeveloped pulpless teeth

Prescription Use  AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Dunn  
(Division Sign-Off)

Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K033585

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